



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/661,453	09/13/2000	Steven M. Ruben	PZ038P1	8927

22195 7590 12/18/2001
HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE, MD 20850

EXAMINER	
MARSCHEL, ARDIN H	
ART UNIT	PAPER NUMBER
1631	8
DATE MAILED: 12/18/2001	

Please find below and/or attached an Office communication concerning this application or proceeding.

<h2 style="margin: 0;">Office Action Summary</h2>	Application No. 09/661,453	Applicant(s) Ruben et al.						
	Examiner Ardin Marschel	Art Unit 1631						
								
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>								
<p>Period for Reply</p> <p>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>1</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.</p> <ul style="list-style-type: none"> - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). 								
<p>Status</p> <p>1) <input type="checkbox"/> Responsive to communication(s) filed on _____</p> <p>2a) <input type="checkbox"/> This action is FINAL. 2b) <input checked="" type="checkbox"/> This action is non-final.</p> <p>3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> 1035 C.D. 11; 453 O.G. 213.</p>								
<p>Disposition of Claims</p> <p>4) <input checked="" type="checkbox"/> Claim(s) <u>1-23</u> is/are pending in the application.</p> <p>4a) Of the above, claim(s) _____ is/are withdrawn from consideration.</p> <p>5) <input type="checkbox"/> Claim(s) _____ is/are allowed.</p> <p>6) <input type="checkbox"/> Claim(s) _____ is/are rejected.</p> <p>7) <input type="checkbox"/> Claim(s) _____ is/are objected to.</p> <p>8) <input checked="" type="checkbox"/> Claims <u>1-23</u> are subject to restriction and/or election requirement.</p>								
<p>Application Papers</p> <p>9) <input type="checkbox"/> The specification is objected to by the Examiner.</p> <p>10) <input type="checkbox"/> The drawing(s) filed on _____ is/are objected to by the Examiner.</p> <p>11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved.</p> <p>12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.</p>								
<p>Priority under 35 U.S.C. § 119</p> <p>13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).</p> <p>a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of:</p> <ol style="list-style-type: none"> 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). <p>*See the attached detailed Office action for a list of the certified copies not received.</p>								
<p>14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).</p>								
<p>Attachment(s)</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;"> 15) <input type="checkbox"/> Notice of References Cited (PTO-892) </td> <td style="width: 50%;"> 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ </td> </tr> <tr> <td>16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</td> <td>19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</td> </tr> <tr> <td>17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____</td> <td>20) <input type="checkbox"/> Other: _____</td> </tr> </table>			15) <input type="checkbox"/> Notice of References Cited (PTO-892)	18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____	16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)	17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____	20) <input type="checkbox"/> Other: _____
15) <input type="checkbox"/> Notice of References Cited (PTO-892)	18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____							
16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)							
17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____	20) <input type="checkbox"/> Other: _____							

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Restriction/Election Requirement

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-7, 9, 10, 14, and 21; drawn to polynucleotides and compositions containing same, classified in Class 536, subclass 23.1; Class 435, subclasses 243, 320.1, and 325; and Class 514, subclass 44. If this group is elected, then the below sequence election requirement also is required.

II. Claim 8, drawn to methods of making a recombinant host cell, classified in Class 435, subclass 440. If this group is elected, then the below sequence election requirement also is required.

III. Claims 11, 12, and 16; drawn to polypeptides, classified in Classes 530 and 514, subclasses 350 and 2, respectively. If this group is elected, then the below sequence election requirement also is required.

IV. Claim 13, drawn to an antibody, classified in Class 530, subclass 387.1. If this group is elected, then the below sequence election requirement also is required.

V. Claim 15, drawn to methods of expression of a polypeptide, classified in Class 435, subclass 69.1. If this

group is elected, then the below sequence election requirement also is required

VI. Claim 17, drawn to methods for preventing, treating, or ameliorating a medical condition, classified in Class 514, subclasses 2 and 44. If this group is elected, then the below sequence election requirement also is required. Also, if this group is elected then a specie election is also required wherein the species are: Specie VIA: polypeptide and Specie VIB: polynucleotide.

VII. Claim 18, drawn to methods of diagnosing based on polynucleotide mutation detection, classified in Class 435, subclass 6. If this group is elected, then the below sequence election requirement also is required.

VIII. Claim 19, drawn to methods of diagnosing based on polypeptide expression detection, classified in Class 435, subclass 7.1. If this group is elected, then the below sequence election requirement also is required.

IX. Claims 20 and 23, drawn to methods of identifying a polypeptide binding partner and said binding partner composition, classified in Class 436, subclass 501. If this group is elected, then the below sequence election requirement also is required.

X. Claim 22, drawn to a method of identifying an activity of a protein in a cell, classified in Class 435, subclass 4. If this group is elected, then the below sequence election

requirement also is required.

Sequence Election Requirement Applicable to All Groups:

In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicant(s) must further elect a single amino acid sequence. For an elected Group drawn to nucleic acid sequences, the Applicant(s) must elect a single nucleic acid sequence (See MPEP 803.04). It is noted that this is a restriction requirement to a single sequence and NOT a species election requirement.

MPEP 803.04 states:

"Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq."

It has been determined that 1(ONE) sequence constitutes a reasonable number for examination purposes under the present conditions. At present the huge number of submissions of claims

directed to various sequences, such as nucleic acids or polypeptides, is so large that the election of 1(one) sequence of this type is now deemed to be practically appropriate so as to not overwhelm the examination and search processes for such claims.

Examination will be restricted to only the elected sequence.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups (I, II, V, VI [polynucleotide specie], and VII); Groups (III and VI [polypeptide specie], VIII, IX, and X); and Group IV are independent inventions because they are directed to different chemical types regarding the critical limitations therein. For Groups (III and VI [polypeptide specie], VIII, IX, and X) the critical feature is a polypeptide; for Groups I, II, V, VI [polynucleotide specie], and VII) the critical feature is nucleic acid; and for Group IV the critical feature is an antibody. It is acknowledged that various processing steps may cause a polypeptide of Groups III etc. to be directed as to its synthesis by a polynucleotide of Groups I, etc., however, the completely separate chemical types of the inventions of the nucleic acid, polypeptide, and antibody Groups supports the undue search burden if both were examined together. Additionally, polynucleotides, polypeptides, and antibodies have been most commonly, albeit not always, separately characterized and

published in the Biochemical literature, thus significantly adding to the search burden if examined together as compared to being searched separately. Also, it is pointed out that processing that may connect two Groups does not prevent them from being viewed as distinct because enough processing can result in producing any composition from any other composition if the processing is not limited as to additions, subtractions, enzyme action, etc. Thus, the three Groupings of (I, II, V, VI [polynucleotide specie], and VII); (III and VI [polypeptide specie], VIII, IX, and X); and (IV) are independent and/or distinct invention types for restriction purposes.

The inventions of Group I and Groups II, V, VI [polynucleotide specie], and VII are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the nucleic acids of Group I can be used in the distinct processes of the inventions of Groups II, V, VI [polynucleotide specie], and VII. One use is directed to recombinant cell preparation, another to polypeptide expression and the others to treatment or diagnosis via nucleic acid binding reactions. Alternatively, the

nucleic acids of Group I can be used in nucleic acid preparatory methods such as PCR etc. which is also a clearly distinct usage of such nucleic acids.

The inventions of Group III and Groups VI [polypeptide specie], VIII, IX, and X are related as product and distinct processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the polypeptides of Group III can be used in the distinct processes of the inventions of Group VI for treatment etc. or in the distinct methods of Groups VIII(diagnosis), IX(binding partner identification), or X(activity identification), or, alternatively, for substrate processing which would be available for an enzymatic activity or for affinity purification if the protein is only a binding protein.

REGARDING THE SPECIE ELECTION REQUIREMENT FOR GROUP VI:

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 17 is generic to Species VIA and VIB.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least

one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

November 27, 2001

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER